IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
COOKEVILLE DIVISION

ANDREW SCOTT RODRIGUEZ,	)	
	)	
Plaintiff,	)	
	)	**No. 2:08-cv-124**
v.	)	
	)	**Judge Aleta A. Trauger**
STRYKER CORPORATION, a Michigan corporation; and STRYKER SALES CORPORATION, a Michigan corporation,	)	**Magistrate Judge Bryan**
	)	
Defendants.	)	

REPLY IN SUPPORT OF STRYKER'S MOTION FOR SUMMARY JUDGMENT

INTRODUCTION

Despite making a rousing jury closing argument, Plaintiff's Opposition to Motion for Summary Judgment ("Opp.") fails to address the three key arguments raised in Stryker's Motion ("MSJ" or "Motion"). He provides no evidence that any Stryker representation proximately caused his alleged injuries. He fails to counter the undisputed evidence that Stryker neither knew nor should have known of any risk of cartilage damage inherent in its pain pump as of Plaintiff's index surgery in November 2004. And he fails to identify the expert testimony necessary to make the predicate showing of "defect" or "unreasonable danger" required for any of his causes of action to proceed under the Tennessee Product Liability Act ("TPLA").

Plaintiff cannot prove proximate cause because he cannot overcome his treating physician's testimony that no Stryker representation played any role in his decision to prescribe Plaintiff a pain pump. With no evidence of proximate cause, Plaintiff's claims

– even were they successfully to run the remaining gauntlet of challenges set forth in the Motion – necessarily fail.

Tennessee law requires Stryker to warn of risks inherent in its pump that were known or knowable from the existing state of scientific knowledge at the time the pump was marketed. By Plaintiff's expert's admission, there was no scientific knowledge associating any cartilage injury – let alone chondrolysis – with the use of pain pumps, even well after Plaintiff's surgery. Because this knowledge did not exist, and thus was not within the ambit of Stryker's constructive knowledge, Stryker had no duty to warn of a risk of which it could not have known. Moreover, the undisputed state of the existing science in November 2004 demonstrates that Stryker's warning conformed to the "state of the art," which forecloses any liability under the TPLA.

Finally, the TPLA requires, as a predicate to any cause of action for product liability, a showing that the product is "defective" or "unreasonably dangerous." Because Plaintiff is alleging failure to warn claims regarding a prescription medical device, he is precluded from proving a "defect" (and at any rate lacks the expert testimony to do so) and from utilizing the "consumer expectations" test to prove "unreasonable danger." The entirety of Plaintiff's claims, therefore, hinges on his satisfaction of the "prudent manufacturer" test, but he has failed to supply the requisite testimony. As a result, each of his claims is foreclosed by the TPLA.

ARGUMENT

I. THERE IS NO EVIDENCE OF PROXIMATE CAUSATION.

Stryker's Motion demonstrates that, even if Plaintiff could prove that Stryker failed to warn of a known or knowable risk inherent in its pump, he nonetheless cannot

prove that such failure caused his injuries. [MSJ at 17, Doc. No. 110.] This is because the testimony of Dr. Kuhn, Plaintiff's treating physician, affirmatively establishes that his prescription of Plaintiff's pain pump was driven by his own training and the medical literature, and not by any information from Stryker – whether via a representative or Stryker's Instructions for Use. [*Id*.] In response, Plaintiff cites to page 68 of Dr. Kuhn's deposition testimony and claims that "Dr. Kuhn testified that he would not have used Stryker's pain pump intra-articularly in November of 2004 if he had known that pain pumps were linked to cartilage damage." [Opp. at 32, Doc. No. 152.]

This is, to put it mildly, a gross mischaracterization of the cited testimony. When read in conjunction with page 67 (which Plaintiff omits, despite including page 66), it is clear that Dr. Kuhn's testimony pertains to local anesthetics, and is not limited in time to before Plaintiff's surgery in November 2004. [Kuhn Depo. at 67:1-68:9, Tucker Decl. ISO Reply Exh. C.][1] It has nothing to do with the pump. There is therefore no evidence indicating that Dr. Kuhn would not have used the pump if he had known of a linkage between it and cartilage damage.

But even if there were, it would still be inadequate to prove causation because it does not contradict Dr. Kuhn's testimony that his prescription of the pump was uninfluenced by any Stryker representation. [MSJ at 17.] In other words, even if Stryker had included in its Instructions for Use precisely the warning Dr. David proposes, Dr. Kuhn's testimony is that he would not have been influenced by it – let alone avoided using Stryker's pump as a result. *King v. Danek Medical, Inc.*, 37 S.W.3d 429, 453 (Tenn. Ct. App. 2000) (failure to warn claim fails for lack of proximate cause where

[1] Tucker's Declaration in support of the MSJ is referred to simply as "Tucker Decl.", whereas Tucker's Declaration in support of Stryker's Reply is referred to as "Tucker Decl. ISO Reply."

plaintiffs cannot show prescribing physician's decision was influenced by any defendant representation such that "had additional warnings been given, the plaintiffs would not have sustained their injuries"). Plaintiff therefore lacks any evidence of proximate cause regardless of the agglomeration of irrelevant facts he includes in his argument, a point he essentially concedes by emphasizing that Dr. Kuhn's phantom testimony is "most important[]."[2] [Opp. at 33.]

Finally, it should be noted in this regard that Plaintiff's Opposition repeatedly alleges that Stryker "actively marketed" or "promoted" its pain pumps for use in the synovial cavity. [*Id*. at 15; *see also id*. at 1, 13, 16, 37.] Typically, Plaintiff makes this allegation unsupported by any evidence. But even when he does cite to evidence, a quick review of it indicates that only a single item even pertains to the allegation. To wit, Plaintiff cites the deposition of Lonnie Paulos, a doctor in Florida who testified that he had discussions with Stryker representatives regarding "use of the pump and where it could be used and in what types of cases in joints." [Paulos Depo. at 34:1-13, Mrazik Declaration in Support of Plaintiff's Opposition to MSJ ("Mrazik Decl.") Exh. 14, Doc. No. 150.]

Plaintiff makes no argument demonstrating that this testimony constitutes "promotion," and Stryker does not concede the point. But even if it were considered to be promotion, it is irrelevant to this case because there is no evidence that it occurred prior to Plaintiff's surgery and, in any event, Dr. Paulos was not Plaintiff's treating physician. [*See* Stryker's Reply to Statement of Additional Material Facts ("Reply to

[2] The relevance of most of the facts is predicated on Plaintiff's implication that the FDA's denial of an application to add the synovial cavity to the pump's indications for use somehow undermines or contradicts Dr. Kuhn's interpretation of the FDA-approved "intraoperative" indication to include the intra-articular space, if that was the location of the operation. [Opp. at 32-33.] Plaintiff does not, however, provide any evidence of the truth of that implication.

SAMF") 29.] Dr. Kuhn was Plaintiff's surgeon, and there is absolutely no evidence that Stryker ever promoted intra-articular use to him. Indeed, he has no recollection of any conversation with a Stryker representative regarding pain pumps and, in any event, never relied on anything they might have said. [Kuhn Depo. at 17:22-18:8, Tucker Decl. Exh. N, Doc. No. 116.] There is no connection between Dr. Paulos' allegation and Plaintiff.

II. COMMENT K FORECLOSES ALL BUT PLAINTIFF'S FAILURE TO WARN CLAIM PURSUANT TO THE TPLA.

Plaintiff misapprehends Stryker's argument regarding the effect of Comment k on the totality of his claims. [Opp. at 7-8 n.4.] Stryker does not argue that Comment k in and of itself operates to foreclose Plaintiff's non-strict liability claims, and thus his authorities to the contrary are inapposite. [MSJ at 10.] The fact remains, however, that the TPLA explicitly incorporates the strict liability standards of "defect" and "unreasonable dangerousness" as predicate burdens of proof to any cause of action for product liability, regardless of theory. *Harwell v. American Medical Systems, Inc.*, 803 F. Supp. 1287, 1298 (M.D. Tenn. 1992) ("[I]t makes no difference whether the complaint is couched in terms of negligence, strict liability or breach of warranty, it has generally been held in the State of Tennessee that in order for a plaintiff to recover under any theory of product liability, the plaintiff must establish that the product was defective [or] unreasonably dangerous at the time the product left the control of the manufacturer."). Comment k, in turn, holds that a prescription medical device is neither defective nor unreasonably dangerous if it is manufactured appropriately and is accompanied with adequate warnings. Restatement (Second) Torts § 402A Comment k. Plaintiff does not dispute that Comment k applies to Stryker's pain pump or that he alleges no manufacturing claim against Stryker. Thus, the undisputed operation of Comment k on

Plaintiff's claims is to narrow the inquiry to a failure to warn because an adequate warning forecloses a finding of defect or unreasonable dangerousness, which in turn forecloses the predicate showing for any cause of action under the TPLA. *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 428-29 (Tenn. 1994) (holding that manufacturers of prescription products discharge their duty under Comment k by distributing them with proper directions and adequate warnings).

III. THERE IS NO EVIDENCE THAT STRYKER FAILED TO WARN OF A RISK OF CARTILAGE INJURY INHERENT IN ITS PUMP OF WHICH IT KNEW OR HAD REASON TO KNOW.

A. Stryker's duty is to warn of known or knowable risks inherent in the use of its pump.

Plaintiff charges Stryker with an imaginative array of purported failures to warn, from failing to direct surgeons in their practice of medicine, to failing to mention the FDA's denial of an application for a synovial use indication on its label, to failing to warn regarding some nebulous danger to cartilage that, though not identified in the scientific literature, was somehow derivable from it. [Opp. at 28-32.] None of these alleged failures has a basis in Tennessee law. Stryker's sole duty is to provide an adequate warning of known or knowable risks. *Witherspoon v. Ciba-Geigy Corp.*, 1986 WL 3138 at * 3 (Tenn. Ct. App. Feb. 12, 1986) (With a prescription medical product, "the standard for liability under negligence and strict liability is essentially the same; namely, did the manufacturer provide an adequate warning?"). Stryker discharges that duty when "it reasonably discloses to the medical profession all risks inherent in the use of [its pump, which Stryker] knew or should have known to exist.[3] *Isbell v. Medtronic,*

[3] This is why Plaintiff's argument that Stryker "failed" to instruct surgeons not to use its pump in a certain way has no basis in law. *See Hofherr v. Dart Industries, Inc.*, 853 F.2d 259, 263-64 (4th Cir. 1988) ("[W]e think the practice of medicine by [prescription product manufacturers and sellers] is not a field in which we should even encourage them to engage, much less require it, as plaintiff would have.")

Inc., 97 F. Supp. 2d 849, 862 (W.D. Tenn. 1998). Thus, Plaintiff must prove that Stryker had actual knowledge of a danger of cartilage injury inherent in its pump, or that it would have known of such a danger when imputed with the scientific knowledge then existing in the relevant literature at the time it was marketed. *Witherspoon*, 1986 WL 3138 at *3 (finding inquiry into what prescription product manufacturer knew or should have known about its products harmful effects "was properly limited to the scientific and medical knowledge available to [the manufacturer]").

B. Stryker had no knowledge or reason to know of any risk of cartilage injury inherent in its pump as of Plaintiff's surgery in November 2004.

1. Stryker had no actual knowledge of any risk of cartilage injury inherent in its pump.

In support of its Motion, Stryker provided statements of fact in support of its assertion that it had no actual knowledge of any risk of cartilage injury. [Stryker's Statement of Undisputed Facts ("SOUF") 7-8, Doc. No. 112.] Plaintiff offers no relevant contradictory facts in response. [Plaintiff's Response to SOUF 7-8, Doc. No. 157.] Indeed, he concedes that Stryker was "ignorant of the danger posed by its pain pump." [Opp. at 14.] It is therefore undisputed that Stryker had no actual knowledge of any risk of cartilage injury arising from its pumps at the time of Plaintiff's surgery.

2. Stryker had no constructive knowledge of any risk of cartilage injury inherent in its pump.

a. The scientific and medical literature disclosed no known risk of cartilage injury associated with pain pumps as of November 2004.

To show a triable issue as to Stryker's constructive knowledge, Plaintiff must demonstrate that the scientific literature as of November 2004 disclosed a known risk of cartilage injury arising from continuous infusion involving a pain pump. Instead,

Plaintiff alleges that Stryker should have derived from the literature some vague possibility that continuous infusion could be "unsafe." [Opp. at 10.] But this allegation is belied by his own admission that "there was inadequate information in the scientific community in 2004 to conclude that intra-articular infusion of medication into the joint space was safe." [*Id*. at 13.] A motion for summary judgment cannot be defeated by claiming that a device is unsafe when the evidence indicates only that it has not affirmatively been proven safe. *King*, 37 S.W.3d at 445. Indeed, by logical necessity, Plaintiff's admission concedes that there was also insufficient information to conclude that the practice was unsafe. Put another way, any risk of cartilage injury associated with continuous infusion was unknown by the scientific community in 2004.[4]

Stryker, however, "cannot be expected to warn of an unknown." *Goode v. Tamko Asphalt Products, Inc.*, 1988 WL 99985 at * 2 (Tenn. Ct. App. Sept. 30, 1988), *reversed on other grounds*, 783 S.W.2d 184, 187 (Tenn. 1989). Neither is Stryker the insurer of its product, or liable for ensuring that it is "incapable of causing injury." *Fulton v. Pfizer Hosp. Prods. Group, Inc.* (1993) 872 S.W.2d 908, 912 (Tenn. Ct. App. 1993). Stryker's duty is to warn of the risks inherent in its device of which it knew or should have known. *Harwell*, 803 F. Supp. at 1299. By Plaintiff's own admission, Stryker had no reason to know from the scientific literature in 2004 that continuous infusion posed any risk of cartilage injury. [Opp. at 13.] Stryker therefore could not have failed to warn of it.

Moreover, the evidence upon which Plaintiff relies is insufficient to trigger Stryker's duty to warn. Preliminarily, Dr. Trippel's cited deposition testimony does not even characterize the import of the literature. As set forth and emphasized in Plaintiff's

[4] Plaintiff implicitly concedes this as well by his allegation that Stryker could not "wait for the scientific community to discover a risk" of cartilage injury. [Opp. at 13.]

Opposition, Dr. Trippel testified only that the articles cited in his (original) report constituted the "information that a pain pump manufacturer … should have been aware of prior to 2005 regarding potential safety of a continuous infusion of local anesthetics into the joint space." [Opp. at 10-11.] This testimony says nothing about whether that information constituted a known risk of cartilage injury inherent in Stryker's pain pump.

More fundamentally, Plaintiff's citation to language in Dr. Trippel's report regarding the safety of continuous injection of local anesthetics is irrelevant to Stryker's duty. By law, Stryker is obliged to warn of risks inherent in the use of its pain pump. *Isbell*, 97 F. Supp. 2d at 862. Dr. Trippel's report, however, relies on a series of articles that do not even refer to pain pumps and are therefore insufficient to trigger Stryker's duty to warn – with one exception that merely proves that the existing scientific knowledge in November 2004 had no inkling of any association, let alone a causal link, between pain pumps and cartilage injury. [Trippel Rpt. at 7-11, Doc. No. 153-1.] That exception is the Petty article, published in 2004, which reported 3 cases of shoulder chondrolysis, one of which "used a pain pump to deliver pain medication into the joint." [*Id*. at 11.]

Dr. Trippel agrees that the Petty article was the first time in the scientific literature that pain pumps and cartilage injury even coincided. [*Id*.] But despite the fact that Petty analyzed the same literature that Dr. Trippel claims constituted notice to Stryker [Trippel Test. at 445:13-446:23, Tucker Decl. Exh. I.], [5] Dr. Trippel concedes that

[5] Dr. Trippel claims that the scientific literature prior to November 2004 constituted notice to Stryker that continuous infusion of local anesthetics was "a risk for causing injury to the cartilage." [Trippel Rpt. at 11.] None of the literature Dr. Trippel cites stands for the proposition. For example, the Nole article specifically concludes: "There does not appear to be any contraindication to the use of intraarticular bupivacaine based on these findings." [Nole Article at 123 (emphasis added), Doc. No. 153-6.] Even Dr. Trippel's impermissible attempt to re-write his report suffers from this fatal defect. He cites the Jaureguito

Petty drew no connection between his single case of pain pump use and any cartilage injury. [*Id*. at 447:22-448:14.] That is why, when asked to identify any scientific literature as of June 2005 that attributed any cartilage damage to any administration of local anesthetic – via pain pump or otherwise – Dr. Trippel had to concede that he could not. [*Id*. at 445:13-23.] In light of Plaintiff's own expert's admission of the lack of any association between pain pumps and a risk of cartilage injury in the scientific literature as of November 2004, Stryker could not have had constructive knowledge of such a risk and thus had no duty to warn.

b. Stryker's meeting with Purdue Pharma disclosed no known risk of chondrolysis at all.

Plaintiff does not argue that Stryker's meeting with Purdue Pharma constituted any notice to Stryker of a risk of cartilage injury inherent in its pump. It is therefore irrelevant to the inquiry at hand. Moreover, even the mild claim he makes, that the meeting gave Stryker "first hand knowledge that local anesthetics were not approved for intra-articular use," is untrue. [Opp. at 11.] The meeting clearly referred to only one local anesthetic, Chirocaine. [*Id*.] Plaintiff does not even attempt to explain how awareness that one particular local anesthetic was not specifically approved for intra-articular injection bears any relevance to Stryker's alleged notice of a risk of cartilage injury inherent in its pain pump – and, in fact, it does not.

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article as "an alert to pain pump manufacturers that prolonged exposure to solutions is likely unsafe for cartilage." [New Trippel Rpt. at 12, Doc. No. 153-2.] But Juareguito specifically concludes: "This study does not suggest any contraindication to the use of intra-articular morphine as a postoperative analgesic." [Juareguito at 631 (emphasis added), Doc. No. 153-11.] Dr. Trippel may not create a triable issue of material fact by citing scientific articles in support of a proposition for which they do not stand. *Baker v. Chevron USA, Inc.*, 680 F. Supp. 2d 865, 887-88 (S.D. Ohio 2010).

c. Stryker's "Simulation Trial Feedback Forms" disclosed no known risk of chondrolysis at all.

Plaintiff's claim that Stryker's "Simulation Trial Feedback" ("STF") forms have something to do with cartilage, chondrotoxicity, or chondrolysis is disingenuous at best.[6] [Opp. at 11-12.] In late 2000, during development of its PainPump 2.0, Stryker conducted a premarket "consumer preference trial" ("CPT"), in which a select number of surgeons were given a prototype of the device for limited use. Afterward, the doctors provided feedback regarding the device's features, function, etc., via an STF form. In two of those forms, one surgeon and one physician's assistant referred generally to "toxicity" as a potential concern. [Mrazik Decl. Exhs. 68-69.] There is literally no evidence to indicate that these forms referred to any sort of cartilage toxicity. In fact, they were referring to systemic cardiac toxicity, a long-known potential complication of local anesthetics, as Plaintiff's own expert concedes. [Parisian Test. at 918:3-920:6, Tucker Decl. ISO Reply Exh. D.] In light of Dr. Trippel's admission that the scientific literature disclosed no risk of cartilage injury associated with pain pumps even as late as June 2005, Plaintiff's allegation that the STF forms put Stryker on notice of a risk of cartilage injury in 2000 is highly suspect. [Opp. at 12.] These forms are completely irrelevant to any notice of any risk of cartilage injury.

C. Plaintiff's cited non-binding authority fails to support any liability for an alleged duty to test.

Plaintiff alleges that Stryker has both a duty to "properly conduct safety tests" and a duty to "research medical literature." [Opp. at 24.] The latter is redundant to Stryker's imputed constructive knowledge of the scientific literature, which is addressed above. As to the former, Plaintiff's resort to non-binding authorities is unavailing. The dearth of

[6] *See* Reply to SAMF 26-28.

Tennessee authority in the Opposition betrays Plaintiff's attempt to import wholesale into Tennessee law a duty the Tennessee courts themselves have not seen fit to adopt.[7]

1. *Kociemba* specifically held that any failure to test is no basis for liability.

Plaintiff's citation to *Kociemba* is particularly ironic, finding as it does that any duty to test is "subsumed" within the duties to design, manufacture, and warn appropriately, so that "a failure to test the product cannot, standing alone, cause any injury." [Opp. at 24;] *Kociemba v. G.D. Searle & Co.*, 707 F. Supp. 1517, 1527 (D. Minn. 1989). In other words, even if *Kociemba* were persuasive, it teaches that any failure to test by Stryker herein is only relevant upon adequate proof that Stryker also failed to warn. As demonstrated in the Stryker's Motion and above, Stryker had no duty to warn and thus could not have failed to do so.

2. *Hoffman* has been repudiated by the Pennsylvania Superior Court.

Plaintiff cites *Hoffman*, a 1973 Third Circuit opinion construing Pennsylvania tort law. [Opp. at 25;] *Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132 (3rd Cir. 1973). The *Hoffman* court more or less assumed, without deciding, that Pennsylvania law recognized a duty to test, because it found the evidence was sufficient to submit the issue to the jury. *Id*. at 140-41. The Pennsylvania Superior Court has since made it clear that *Hoffman* misconstrued Pennsylvania law.

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[7] Plaintiff's citation to an isolated, unpublished, 30-year old decision does not mitigate this conclusion. [Opp. at 12-13.] The language Plaintiff cites from *Allen* was simply excerpted from a 5th Circuit decision, and in any event has never been cited with approval (or at all) by any other Tennessee court, let alone in support of the purported duty to test. *Allen v. Upjohn Co.*, 1981 WL 649508 at *4 (Tenn. Ct. App. Dec. 30, 1981). Indeed, the concept of a duty to test appears to be largely absent from Tennessee precedent. Though *Smith* contains an uncited reference to a duty to test in ruling on a motion *in limine*, it appears to be referring to the regulatory duty of a prescription drug manufacturer who actively promoted its off-label use. *Smith v. Pfizer, Inc.*, 2010 WL 1754443 at *2 (M.D. Tenn. Apr. 30, 2010). Finally, even if the duty in *Allen* were applied, it is explicitly circumscribed by "the dangers involved." *Allen*, 1981 WL 649508 at *4. Where, as here, the danger alleged was scientifically unknowable, the duty does not apply.

In *Lance*, the appellant cited *Hoffman* for the proposition that Pennsylvania law acknowledged a duty to test, from which her novel claims for "unreasonable marketing" and "negligent failure to withdraw" were derived and were therefore cognizable. *Lance v. Wyeth*, 4 A.3d 160, 168 (Penn. Super. Ct. 2010). The court's response was emphatic: "Regardless of the *Hoffman* decision, which is not binding on this Court, Pennsylvania law has not recognized an independent tort for negligent failure to test. In fact, we have held that the claim for negligent failure to test is not a viable cause of action recognized by our courts." *Id*. (citations and punctuation omitted). It went on to align Pennsylvania's position regarding any duty to test with *Kociemba*: "If there is a duty to test and/or inspect in Pennsylvania, it does not exist as an independent cause of action, but rather, is subsumed within Appellant's other claims." *Id*. (quoting *Kociemba*, 707 F. Supp. at 1527 ("The duty to test is a subpart of the other three duties because a breach of the duty to test cannot by itself cause any injury.")).

3. Plaintiff misconstrues *Proctor*.

Plaintiff seriously misconstrues *Proctor*, which is a case about a drug manufacturer's actual knowledge, not its ignorance. [Opp. at 25-26.] *Proctor* involved Upjohn's drug Depo-Medrol, a corticosteroid that was approved by the FDA for treatment of various inflammatory bodily disorders. *Proctor v. Davis*, 291 Ill. App. 3d 265, 268 (1997). Almost immediately, physicians began using Depo-Medrol for the non-FDA approved use of intra-ocular injection. *Id*. at 269. Over the ensuing years, Upjohn received numerous "drug experience reports" of various adverse events associated with the use of Depo-Medrol, several of which concerned vision loss after intra-ocular injection. *Id*. at 274-75. Upjohn did not change its warnings and thereafter Proctor was

injected intra-ocularly with Depo-Medrol and eventually went blind. *Id*. at 275-76. Proctor filed suit against Upjohn for, *inter alia*, failure to warn and the jury returned a verdict in his favor. *Id*. at 276. Upjohn appealed, claiming that the risk was too remote to require a warning. *Id*. at 277.

The appellate court observed that, under Illinois law, Upjohn was obligated to warn if it "knows or should know that harm might occur if no warning is given." *Id*. Critically, the court then found that "[t]he evidence revealed that Upjohn knew of Depo-Medrol's dangerous propensities before the instant occurrence took place." *Id*. at 278 (emphasis added). This finding of Upjohn's actual knowledge refutes Plaintiff's claim that the *Proctor* court "held that the defendant's ignorance of the potential dangers its untested drug posed amounted to a breach of its duty of care." [Opp. at 25.] *Proctor*'s outcome turned on Upjohn's actual knowledge of its product's risks, not the unknown results of testing that Upjohn did not conduct. *Proctor* is therefore inapposite.

4. *Lockwood* and *Hawkinson* are inapposite.

Lockwood is worthy of no more attention than Plaintiff's "see also" citation suggests. [Opp. at 26.] The language lifted for inclusion in the Opposition does not even appear in the *Lockwood* opinion. It is from the jury instructions in the trial below, which the appellate court appended to its opinion without analysis. *Lockwood v. AC & S, Inc.*, 109 Wash. 2d 235, 241 n.3, 269 (1987).

Plaintiff's citation to *Hawkinson* is facially inapposite; none of its quoted language invokes or pertains to a duty to test. [Opp. at 26.] Plaintiff also conflates its strict liability and negligence analysis. The court therein did not, as Plaintiff claims, dismiss the defendant's strict liability defense on negligence grounds. [Opp. at 26;]

Hawkinson v. A.H. Robins Co., Inc., 595 F. Supp. 1290, 1309 (D. Colo. 1984) (noting that "a claim of negligence is distinct from the plaintiffs' claims based on the Restatement (Second) of Torts § 402A").

At any rate, *Hawkinson*'s negligence analysis is premised on Colorado law, which imputes liability for failing to warn as a "reasonably prudent pharmaceutical company" would. *Id*. at 1308. This standard is fundamentally different from Tennessee's, which requires the manufacturer to warn of known or knowable risks inherent in its product, and thus *Hawkinson*'s negligence analysis is inapposite. *See supra*, Section III.A. Moreover, *Hawkinson*'s language faulting the defendant for failing to control unknown risks is apparently an infelicitous reference to the defendant's ignorance of "the state of knowledge within the medical profession" at the time, meaning they were "unknown" to the defendant but "knowable" from existing scientific knowledge. *Hawkinson*, 595 F. Supp. at 1307-08. Finally, to the extent it can be construed as holding a defendant strictly liable for failing to warn of its own lack of knowledge, no court has cited *Hawkinson* for this proposition, and the 10th Circuit has clearly held that Colorado law is contrary. *Oja v. Howmedica, Inc.*, 111 F.3d 782, 791 (10th Cir. 1997) (strict liability failure to warn in Colorado requires showing that defendant failed to warn of particular risks that were known or knowable).

D. Stryker had no duty to warn of the FDA's disposition of Stryker's application to add a specific indication for the synovial cavity to the instructions for use, because it raised no known or knowable risk inherent in its pump.

Plaintiff's repeated assertions or implications that Stryker twice applied to the FDA for a synovial indication and was twice denied contradict his own evidence. [Opp. at 1, 13.] The first such application was by McKinley Medical, not Stryker. [Plaintiff's

Statement of Additional Material Facts ("SAMF") 11, Doc. No. 157.] McKinley subsequently withdrew that application, but the FDA approved it anyway – though it later corrected its error by revising its approval to remove the synovial cavity indication. [*Id.* at 14-16.] When Stryker later brought a similar application, the FDA would not agree to it, not because it was unsafe, but "because there was no predicate device." [Petty Depo. at 198:19-199:3, Mrazik Decl. Exh. 10.] Indeed, the ascertainment of a predicate device is the sole inquiry of the 510(k) process Stryker utilized. [*See* MSJ at 5.]

Plaintiff's attempt to transform the FDA's disposition of Stryker's application for a synovial indication into some sort of safety determination falls flat.[8] Preliminarily, Stryker's constructive knowledge of the risks inherent in its pump is limited by law to scientific knowledge then existing in the relevant literature, not regulatory approvals or disapprovals. *Witherspoon*, 1986 WL 3138 at *3 (finding inquiry into what prescription product manufacturer knew or should have known about its products harmful effects "was properly limited to the scientific and medical knowledge available to [the manufacturer]"). Stryker therefore has no duty to "warn" of the FDA's administrative decisions at all.

In any event, none of the evidence Plaintiff cites refers to a safety determination by the FDA. [Opp. at 13.] In fact, by Plaintiff's own assertion, the FDA denied Stryker's application pursuant to the 510(k) process simply "because there was no other equivalent device that had been approved for such use." [SAMF 36.] There is no evidence that an FDA determination regarding substantial equivalence bears any safety determination at

[8] Contrary to Plaintiff's claims and his own evidence, the FDA did not deny or disapprove the use of the pump in the synovial cavity; it declined to approve an indication for such use on its label. [Opp. at 15.] Plaintiff's purported FDA expert, Dr. David, is particularly careless in this regard. [Opp. at 22 (quoting David's report for proposition that "Stryker was refused approval for applying the pumps in the joint space");] *see also infra* Section IV.B.

all, and it obviously does not constitute scientific or medical knowledge of a risk of cartilage injury inherent in its pump sufficient to trigger Stryker's duty to warn.

Moreover, Plaintiff alleges only that the FDA's determination "put Stryker on notice that the safety of intra-articular use was unproven." [Opp. at 13.] This is fundamentally different from notice that the use was unsafe. Again, a motion for summary judgment may not be defeated by claiming that a device is unsafe when the evidence indicates only that it has not affirmatively been proven safe.[9] *King*, 37 S.W.3d at 445.

IV. EVEN IF COMMENT K DID NOT FORECLOSE ALL BUT PLAINTIFF'S FAILURE TO WARN CLAIMS, PLAINTIFF STILL CANNOT SATISFY THE PREDICATE SHOWING UNDER THE TPLA THAT STRYKER'S PAIN PUMP WAS DEFECTIVE OR UNREASONABLY DANGEROUS.

A. Stryker's pump was neither defective nor unreasonably dangerous because it conformed to the state of the art.

In determining whether a product is defective or unreasonably dangerous, "the state of scientific and technological knowledge available to the manufacturer or seller at the time the product was placed on the market, rather than at the time of injury, is applicable." Tenn. Code Ann. § 29-28-105(b). The state of the scientific knowledge is better known as the "state of the art." *Clarksville-Montgomery County School System v. U.S. Gypsum Co.*, 925 F.2d 993, 1005 (6th Cir. 1991). A product warning conforms to the "state of the art," and is therefore neither defective nor unreasonably dangerous, when it represents the best scientific knowledge available at the time it was placed on the market. *Abbott v. American Honda Motor Co.*, 682 S.W.2d 206, 211 (Tenn. Ct. App.

[9] This is why Plaintiff's passing complaint that "Stryker never informed physicians that use of the pain pumps in a joint space had not been studied or tested for patient safety" is also inapposite. [Opp. at 31.] Plaintiff's attempt to impose on Stryker a duty to inform of the absence of an ultimate safety determination is contrary to Stryker's sole and specific duty to warn of known or knowable risks inherent in the use of its product under Tennessee law. *Isbell*, 97 F. Supp. 2d at 862.

1984); *Harwell*, 803 F. Supp. at 1298. In its Motion for Summary Judgment and above, Stryker has demonstrated that the best scientific knowledge available, even at the time of Plaintiff's surgery in November 2004, disclosed no known risk of cartilage injury associated with pain pumps.

In opposition, Plaintiff argues that Stryker's pump did not conform to the state of the art because Stryker did not warn, did not test, and did not conform to FDA regulations. [Opp. at 9.] To the extent that Plaintiff's failure to warn and failure to test arguments are relevant to the state of scientific knowledge available to Stryker at the time its pump was placed on the market, Stryker has refuted their contentions above by again setting forth undisputed evidence that the existing scientific literature contained no knowledge of any risk of cartilage injury inherent in, or even associated with, pain pumps. *See supra*, Section III.B.2.a. Plaintiff's argument that a failure to conform to FDA regulations has some relevance to the state of the art has no basis in law.

Plaintiff contends that FDA regulations are somehow relevant to determining the "state of the art," ostensibly because the Court may consider "whether Stryker complied with 'the customary designs, methods, ***standards*** and techniques of manufacturing, inspecting and ***testing*** by other manufacturers or sellers of similar products.'" [Opp. at 9-10 (emphasis in original).] Plaintiff's odd use of emphasis is no doubt intended to divert attention from the end of his quote, which makes it obvious that the TPLA invokes industry custom, not federal regulations. Moreover, the only case Plaintiff cites for his novel proposition is *Boyd*, which even Plaintiff concedes deals only with "industry standards." [Opp. at 14.] And, in fact, *Boyd* contains no reference to federal regulations in its determination of the "state of the art." Indeed, there is no reason why it would.

While industry custom and practice are clearly relevant in ascertaining what attributes are scientifically or technologically feasible for a given product, federal regulations – particularly of the FDA variety – are concerned instead with safety and efficacy. The latter, by their very nature, are irrelevant to a determination of the state of the art, and Plaintiff's argument to the contrary has no power.

B. Plaintiff either is precluded from proving or has failed to prove that Stryker's pump was defective.

Plaintiff's Opposition does not dispute that Tennessee law requires expert testimony tracing his injury to a specific error in the particular device he used in order to establish defect. [MSJ at 14, Opp. at 15-16.] Instead, he argues only that he met the requirement through Dr. David's opinion that Stryker should have included a statement on its label that the "FDA did not approve application of this device into the synovial space." [David Decl. Exh. 1 at 12, Doc. No. 155.] Preliminarily, Dr. David's recommended statement is contrary to the undisputed facts and to FDA policy. Both parties agree that the FDA withheld approval "to market [ ] pain pumps for use in the synovial space", not of the use itself [*See*, *e.g.*, SAMF 11, 32 (emphasis added).] This is because, as Plaintiff's FDA expert should know, the FDA does not regulate device use by physicians, only device marketing by manufacturers. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 351 n.5 (2001).

Even if Dr. David's suggested statement were granted meaning in accord with the uncontested facts of the case and the FDA regulations he purports to construe, it still does not prove a defect. Product defect "is not demonstrated by simply showing that there was a better, safer, or different design which might have avoided the injury." *Shoemake v. Omniquip Int'l, Inc.*, 152 S.W.3d 567, 573 (Tenn. Ct. App. 2003). Plaintiff's expert must

also establish, with an adequate scientific basis, that the alleged improvement to the product was known at the time of manufacture to prevent the defect, or that the existing product attribute that the expert faults was known at the time to be dangerous. *Harwell*, 803 F. Supp. at 1298. Dr. David has failed to explain how his allegedly improved warning was known as of November 2004 to prevent cartilage injury or that Stryker's actual warning was known at that time to be dangerous. Nor could he: Stryker has demonstrated above that no one in the scientific community had even conceived of any link between pain pumps and cartilage injury at that point. *See supra* Section III.B.2.a. Put another way, Dr. David's suggested statement indicates, at most, only a better pump warning, not that the actual warning was defective. This is insufficient evidence of a defect. *Id*. at 1300.

In any event, Plaintiff is foreclosed by law from proving a product defect as the predicate showing under the TPLA – at least as to his failure to warn claims. "'[D]efective condition' as the term is contemplated by the Act has no application to the ordinary failure to warn case. This is so because one cannot be expected to warn of an unknown." *Goode*, 1988 WL 99985 at * 2. Because the option of showing a defective condition is legally eliminated, "it is incumbent upon a plaintiff in [a failure to warn] case to show that the product was unreasonably dangerous when it left the manufacturer's control." *Id*. at *3; *see also Smith v. Guadino*, 911 F. Supp. 296, 299 (E.D. Tenn. 1996) ("To demonstrate an inadequate warning, a plaintiff must establish the product is unreasonably dangerous by reason of defective warning and must prove that the inadequate labeling proximately caused the claimed injury."). Thus, whether by law or

by deficits in his own expert's testimony, Plaintiff is precluded from demonstrating a product defect.

C. Plaintiff cannot prove that Stryker's pump was unreasonably dangerous.

1. The consumer expectation test is inapplicable.

Stryker's Motion points out that the consumer expectation test has no application to a prescription medical product like a pain pump. [MSJ at 14-15.] The Opposition's reliance on *Jackson* for the proposition that "[t]he consumer expectation test is applicable to any products liability case" is eviscerated by this Court's own precedent. [Opp. at 17 (emphasis omitted).] In *Coffey*, this Court explained that, "although *Jackson* stands for the proposition that the consumer expectation test is theoretically applicable to all situations, even that Court acknowledged that ordinary consumers would have no expectations regarding certain products …." *Coffey v. Dowley Mfg., Inc.*, 187 F. Supp. 2d 958, 969 (M.D. Tenn. 2002) (emphasis added), *aff'd*, 89 Fed. Appx. 927, 2003 WL 23156640 (6th Cir. 2003). Thus, "the *Jackson* Court continues to recognize that … the [consumer expectation] test may be inadequate in cases involving complex products that are not familiar to ordinary consumers. In those situations, the prudent manufacturer test is the sole useful test for assessing [an] unreasonably dangerous condition." *Id.* (emphasis added) ("Although Plaintiffs may theoretically utilize the consumer expectations test, this Court finds that Plaintiffs will be unable to make out a claim for products liability without the use of an expert."); *accord Brown v. Raymond Corp.*, 432 F.3d 640, 643-47 (6th Cir. 2005) (*Brown II*). Plaintiff does not dispute that an "ordinary person" would have no knowledge or expectation about the prescription medical device at issue herein. *King*, 37 S.W.3d at 445 ("[A]n ordinary consumer would not have the

medical knowledge or a basis of expectations about the safety of [a medical device].”). The consumer expectations test is therefore inapplicable as a practical matter, if not as a matter of law.

2. Plaintiff has failed to provide sufficient evidence to apply the prudent manufacturer test.

As Stryker explains in its Motion, Plaintiff cannot utilize the prudent manufacturer test without expert testimony – including a risk-utility analysis balancing the 7 factors set forth in *Ray* – regarding prudence of the manufacturer’s decision to market the product assuming knowledge of its dangerous condition. [MSJ at 15-16;] *Ray v. BIC Corp.*, 925 S.W.2d 527, 533 n.10 (Tenn. 1996).

a. None of Plaintiff’s experts even purports to address the prudent manufacturer test.

In opposition, Plaintiff can point to no expert testimony that satisfies even the predicate to the prudent manufacturer test – not a single one of his experts offers any opinion on the assumption that Stryker knew of the dangerous condition Plaintiff alleges. [Opp. at 18-23.] Neither does he offer any expert testimony that engages in the required risk-utility analysis. [*Id*.] Instead, Plaintiff conducts a scavenger hunt amidst the reports and testimony of his general causation expert, his FDA expert, and his unretained treating physician, retrieving bits and pieces of language that bear some passing resemblance to a few of the test’s individual factors. [*Id*.] This attempt to gloss over the fact that none of his experts even addressed the prudent manufacturer test or a risk-utility analysis, let alone rendered an opinion on them, is patently insufficient. *See Johnson v. Manitowoc Boom Trucks, Inc.*, 406 F. Supp. 2d 852, 867 (M.D. Tenn. 2005) (“The plaintiff cannot rely on contrived snippets of the defendant’s expert’s testimony to mask her failure to produce a competent expert of her own.”)

b. Plaintiff's expert evidence fails to address the efficacy of alternative warnings, which is critical to the prudent manufacturer test in a failure to warn case.

When expert testimony is proffered in a failure to warn case utilizing the prudent manufacturer standard, the expert must address not only alternative warnings, but the probable efficacy of those warnings and whether that efficacy is susceptible to testing. *Brown v. Raymond Corp.*, 318 F. Supp. 2d 591, 600 (W.D. Tenn. 2004) (*Brown I*). Without addressing the efficacy of his proposed warnings, an expert has "no basis" to conclude that a product is unreasonably dangerous pursuant to the prudent manufacturer test. *Id*. As a result, an expert's "failure to propose alternative warnings subject to empirical testing render[s] his testimony unreliable and irrelevant to the trier of fact." *Brown II*, 432 F.3d at 648 (emphasis added).

Here, Dr. David is the only expert who even suggests an alternative warning. But having opined that Stryker's warning should have referred to the FDA's regulatory determination, he completely fails to indicate whether and to what extent such an alternative warning would be effective, and whether and how its efficacy is susceptible to empirical testing. [David Decl. Exh. 1 at 12.] Aside from providing further evidence that Dr. David was not even attempting to address the prudent manufacturer test, this deficit denies him any basis for concluding that Stryker's pump was unreasonably dangerous under the prudent manufacturer test. *Brown I*, 318 F. Supp. 2d at 600. Because no other expert even addresses alternative warnings, Plaintiff lacks competent expert testimony proposing alternative warnings subject to empirical testing and therefore cannot meet his burden of proof under the prudent manufacturer test.

c. Plaintiff may not rely on testimony from his unretained treating physician to provide evidence regarding the prudent manufacturer test.

Critical portions of even the meager pastiche of testimony fragments Plaintiff assembles are inadmissible opinions. Plaintiff purports to rely on the testimony of Dr. Kuhn, his treating physician, whom he disclosed as an unretained expert without a Rule 26 report.[10] "[T]reating physicians [may] testify without filing expert reports so long as they [do] not purport to testify beyond the scope of their own diagnosis and treatment." *Fielden v. CSX Transp., Inc.*, 482 F.3d 866, 870 (6th Cir. 2007); *Bekaert Corp. v. City of Dyersberg*, 256 F.R.D. 573, 576 (W.D. Tenn. 2009) (expert report not required for treating physician if opinion "will be limited to testimony based on his personal knowledge of the factual situation"). This limitation is necessary because "permitting treating physicians to testify in all circumstances without providing expert reports … would permit circumvention of the policies underlying the expert report requirement. A party might attempt to avoid Rule 26(a)(2)(B)'s requirement by having a treating physician testify on an issue instead of having an expert do so." *Fielden*, 482 F.3d at 870. That is precisely the case here. Despite disclosing Dr. Kuhn solely as a treating physician, Plaintiff now seeks to offer his testimony as an expert regarding "whether, balancing all the relevant factors, a prudent manufacturer would market the [pump] despite its dangerous condition." *Coffey*, 187 F. Supp. 2d at 968; [Opp. at 20-21.] The scope of this testimony is well beyond Dr. Kuhn's diagnosis and treatment of Plaintiff, and may not be considered by the Court. *See* Stryker's "Objections to Supplemental Report of Stephen Trippel, M.D., and Improper Opinions of John Kuhn, M.D.", filed

[10] Plaintiff disclosed Dr. Kuhn without "a summary of the facts and opinions to which the witness is expected to testify," as required by FRCP 26(a)(2)(C)(ii). [Plaintiff's Expert Disclosures, Doc. No. 85]

herewith; *In re Aredia and Zometa Prods. Liab. Litig.*, 2009 WL 2496833 *3 (M.D. Tenn. Aug. 13, 2009) (holding the court could not consider, for purposes of summary judgment, the opinions of treating physician who had not filed expert report).

d. The remaining scraps of expert testimony are inapposite to the prudent manufacturer test factors.

Without Dr. Kuhn's deposition excerpts, Plaintiff's own tally indicates he has absolutely no expert testimony regarding 4 of the 7 factors under the prudent manufacturer test. To wit, Plaintiff identified only Dr. Kuhn's inadmissible testimony regarding the third factor (substitute product availability) [Opp. at 20]; he essentially concedes no relevant testimony for the fourth (alternate design) and fifth (user ability to avoid danger) factors, and at any rate the only testimony he proffers is Dr. Kuhn's [*id*. at 20-21]; he does not even mention the seventh factor (feasibility of loss spreading). The testimony he cites for the remaining 3 factors is inapposite.

(1) Plaintiff offers no expert testimony addressing the utility of the pump to the user or the public.

The first factor is the "usefulness and desirability of the product – its utility to the user and to the public as a whole." *Ray*, 925 S.W.2d at 533 n.10. Plaintiff's citation to Dr. Trippel's report language regarding efficacy of pumps is inapposite. [Opp. at 20.] Even if the pumps were "not particularly effective," that does not mean they were not useful, and in any event, Dr. Trippel says nothing about how the purported lack of efficacy affected the utility and desirability of the product to the user or the public. [*Id*.] In short, Dr. Trippel's testimony fails to address the core of the first factor.

(2) Plaintiff offers no expert testimony addressing the likelihood or probability of serious injury.

The second factor is "the safety aspects of the product – the likelihood that it will cause injury, and the probable seriousness of the injury." *Ray*, 925 S.W.2d at 533 n.10. In response, Plaintiff cites Dr. Trippel's report language: "Any careful and safety-conscious manufacturer who wanted to investigate the safety of intra-articular use of their pain pumps would have realized studies that focused on the safety of intra-articular use of pain pumps were not readily available, and were apparently lacking." This has literally nothing to do with the likelihood of injury. [Opp. at 20.] Plaintiff claims the following Trippel report language addresses the seriousness of chondrolysis: "One effect on the chondrocytes of having the synovial fluid replaced by unphysiologic solutions is that they do not have their nutrition anymore and they can become sick and die. Once a cartilage cell is dead, it is forever gone." [*Id*.] At most, this describes the process by which chondrolysis might be produced, not how serious an injury it is. At a bare minimum, Dr. Trippel would have to address the implications of dead cartilage cells for a patient. Plaintiff identifies no such testimony, however, and thus the likelihood and seriousness of chondrolysis arising from pump use remain unaddressed.

(3) Plaintiff offers no expert testimony addressing the user's anticipated awareness of the danger or the existence of suitable warnings.

The sixth factor is "the user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions." *Ray*, 925 S.W.2d at 533 n.10. In response, Plaintiff claims that "Dr. Trippel states that the dangers inherent in using the pain pump in the intra-articular space were avoidable," but

provides no specific quotation. [Opp. at 21.] The 8 pages of Dr. Trippel's report that Plaintiff cites do not, in fact, contain such a statement. Even if they did, there is still no testimony regarding "the user's anticipated awareness of the dangers inherent in the product." *Ray*, 925 S.W.2d at 533 n.10. In response to the requirement of expert testimony addressing "the existence of suitable warnings or instructions," Plaintiff points to Dr. Trippel's testimony regarding Stryker's purportedly unsuitable warnings. In short, no portion of the sixth factor was addressed by Plaintiff's experts.

(4) Plaintiff cannot manufacture the crucial testimony his experts failed to provide.

Plaintiff concludes by offering the hyperbolic assertion that Dr. David's report "squarely addresses the prudent manufacturer test and goes above and beyond what Tennessee requires." [Opp. at 21.] In reality, Plaintiff offers not a single example of a specific aspect of Dr. David's opinion that answers a specific factor of the prudent manufacturer test. All he can offer is Dr. David's use of the phrase "reasonably prudent manufacturer." [*Id*. at 21-23.] But the phrase is not a magic incantation; merely invoking it does not substitute for the analysis required under the test, taking into account the factors enumerated by the Tennessee Supreme Court in *Ray*. Dr. David has done no such analysis, and has failed to address any of those factors.

Indeed, none of Plaintiff's experts have. Faced with a dearth of necessary expert testimony applying the only test he can utilize in order to meet his predicate showing of unreasonable danger under the TPLA, it is not surprising that Plaintiff would attempt to manufacture it. The fact remains, however, that general causation testimony, FDA regulatory testimony, and treating physician testimony – however finely parsed – cannot be forced to speak to factors they were never intended to address. Even if, as Plaintiff

argues, he could escape summary judgment without expert testimony addressing every single factor of the prudent manufacturer test, he clearly cannot do so without competent testimony addressing at least some of them. [Opp. at 19-20.] However, he has produced none, and has therefore failed to satisfy the only applicable test of the only available predicate showing under the TPLA. All of Plaintiffs claims must therefore fail.

V. EVEN IF PLAINTIFF'S IMPLIED WARRANTY CLAIMS WERE NOT PRECLUDED BY COMMENT K AND THE TPLA, THERE IS NO EVIDENCE TO SUPPORT THEM.

Plaintiff's arguments regarding Stryker's alleged breaches of implied warranties are foreclosed in triplicate. The TPLA precludes liability for any product liability claim, including for breach of implied warranty, without a showing of product defect or unreasonable dangerousness. *Tatum v. Cordis Corp.*, 758 F. Supp. 457, 460 (M.D. Tenn. 1991). Thus, Plaintiff's claims are first foreclosed because Stryker warned of all known or knowable risks inherent in its pump, which precludes a finding of defect or unreasonable danger pursuant to Comment k. *See supra*, Sections III.A-III.B.2.a. Second, Plaintiff's claims are foreclosed because the pump conformed to the state of the art, and in any event he cannot prove defect or unreasonable danger pursuant to the TPLA. *See supra*, Section IV. Third, Plaintiff's claim for implied warranty of merchantability is foreclosed because he has failed to offer any evidence that Stryker's pump would not pass without objection in the trade.[11] Similarly, Plaintiff's claim for implied warranty of fitness for a particular purpose is foreclosed because Dr. Kuhn's testimony indicates he had nothing to do with the selection of a Stryker pain pump over

[11] Plaintiff's sole citation to Dr. David's expert report is incompetent in this regard because he is not a medical doctor and therefore cannot testify –and has not testified – to the standards of the relevant trade, i.e., orthopedic surgeons. [Opp. at 35 n.15;] *Harwell*, 803 F. Supp. at 1298 (expectations of product usable only by highly trained specialists must be proven via expert testimony).

any other pump, but merely used whatever pump the facility happened to have.[12] [MSJ at 18.] Thus, he did not select a Stryker pump at all, let alone rely on Stryker's skill or judgment in selecting or furnishing it. [*Id*.]

VI. THERE IS NO EVIDENTIARY BASIS FOR PUNITIVE DAMAGES.

Plaintiff's entire punitive damages argument is undone by his citation of Tennessee law in the first paragraph. *Hodges* stands for the proposition that no punitive damages liability may attach to Stryker without clear and convincing evidence that Stryker was aware of and consciously disregarded a substantial and unjustifiable risk of chondrolysis to Plaintiff. HODGES CITE; [Opp. at 36.] Here, there is no dispute that Stryker lacked even the predicate awareness required under the punitive damages statute, let alone a conscious disregard of it. Indeed, Plaintiff affirmatively alleges that Stryker was "ignorant of the danger posed by its pain pump." [Opp. at 14.] Moreover, Stryker has demonstrated that the state of the scientific knowledge did not allow for it to have known of any risk of cartilage injury arising from its pump, and that the FDA's denial of an application for an indication for use in the synovial cavity did not give rise to a known or knowable risk inherent in its pump. *See supra*, Section III.B.2.a; [*cf*. Opp. at 37-39.] Indeed, the scientific literature still will not impute causation of chondrolysis to pain pumps, and the FDA – as of February 2010 – will not either. [MSJ at 7-8.] There is simply no evidence that Stryker was – or even should have been – aware of a substantial risk of cartilage damage inherent in its pump, let alone consciously disregarded it. Punitive damages are therefore inappropriate.

[12] Plaintiff's citations to other portions of Dr. Kuhn's deposition are inapposite because they do not address, let alone contradict, this testimony. [Opp. at 36.]

CONCLUSION

For the foregoing reasons, Stryker's Motion for Summary Judgment should be granted in its entirety.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 20, 2010, a copy of the foregoing document was filed electronically. Notice of this filing will be sent to the following parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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